DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 13, 2008 has been entered.

Status of the Claims

2. This action is in response to papers filed March 13, 2008 in which claims 75, 82-85 were amended and claim 106 was added. The amendments have been thoroughly reviewed and entered.

Applicant's arguments have been thoroughly reviewed and considered. Any objection/ rejection not repeated herein has been withdrawn by the Office.

Claims 75, 77, 79-90, 92-102, and 106 are under prosecution.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 106 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 106 recites "said detection zone is disconnected from said second flow path when in its first position, and said detection zone is disconnected from said first flow path when in its second position". The Examiner can not locate any disclosure in the specification which supports the limitation that the detection zone is "disconnected" from the second flow path when in its first position and "disconnected" from the first flow path when in its second position. Nor had Applicant cited where such support can be found in the specification. Thus, the claim appears to contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 75, 77, 79-90, 99-102, and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by Bunce et al. (US Patent No. 5,198,193), hereinafter "Bunce".

Bunce teaches an immunoassay analytical test apparatus for screening for the presence of an analyte in a sample of body fluid (i.e., blood; col. 3, line 18; see Fig. 5 and Fig. 20 of Bunce) The apparatus of Bunce comprises:

(a) a first flow path 10e including a sample receiving zone for receiving the sample;

(b) a second flow path 20e including non immobilized labeled immunoreactive material that can interact with the analyte;

(c) a mobile phase receiving zone for receiving a mobile phase 61 from a separate container or store 60 (as recited in claims 101, 102). The mobile phase receiving zone being in communication with the first and second flow paths, and the mobile phase receiving zone (e.g., container 60) is spaced "downstream" from the sample receiving zone along the first flow path 10e; and

(d) a detection zone 40e including immunoadsorbent 32a for binding the analyte present in the sample.

The detection zone of Bunce is manually moveable (i.e. physically movable) in sequence from a first position in communication with the first flow path 10e through expandable zone 23e to a second position in communication with the second flow path through expandable zone 24e (as recited in claims 77-78, and 91). Thus, when the detection zone 40e is in its first position the sample receiving zone is spaced downstream (shown below; Fig. 5) from the detection zone 40e along the first flow path 10e and there is flow of the sample in the mobile phase from the sample receiving zone to the detection zone 40e, whereby the analyte is allowed to substantially bind with the

immunoadsorbent. Note that expandable zone 23e "disconnects" and connects the detection zone 40e from the first flow path 10e and the expandable zone 24e "disconnects" and connects the detection zone 40e from the second flow path 20e (see Fig. 5).

Furthermore, when the detection zone of Bunce is in its second position there is flow of the labeled immunoreactive material in the mobile phase to the detection zone 40e without passing through the sample receiving zone in the first flow path 10e, whereby the labeled immunoreactive material is allowed to substantially bind to the analyte, so as to provide an indication of the presence of the analyte in the sample (see Bunce beginning at col. 5, lines 24-47.) The various reagents for use with the apparatus are described in Bunce beginning at col. 12, line 32.

With respect to the "Markush-type" claims 79-81, the first flow path includes a material selected from the group consisting of unlabeled immunoreactive material being upstream of the sample receiving zone (see col. 3, lines 20-55).

Regarding claims 82-85, 99-100, the first and second flow paths of Bunce, potentiate flow towards the detection zone by capillary action (see col. 1, lines 37-42).

With respect to claims 86-89, written in a Markush format, Bunce teaches a material absorbent to the mobile phase as disclosed beginning at col. 1, line 37.

Regarding claim 90, the apparatus of Bunce includes a sink 50 for collection of fluid exiting the detection zone.

7. Claims 75, 77, 79-90, 99-102, and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al. (US Patent No. 5,275,785), hereinafter "May".

May teaches an immunoassay analytical test apparatus for screening for the presence of an analyte in a sample of body fluid (i.e., blood.) The apparatus of May comprises:

(a) a first flow path 4 including a sample receiving zone for receiving the sample;

(b) a second flow path 3 including non immobilized labeled immunoreactive material that can interact with the analyte (col. 6, lines 55-62);

(c) a mobile phase receiving zone for receiving a mobile phase from a separate container or store 6 (as recited in claims 101, 102.) The mobile phase receiving zone being in communication with the first and second flow paths and the mobile phase receiving zone is spaced downstream from the sample receiving zone along the first flow path; and

(d) a detection zone 8 including immunoadsorbent for binding the analyte present in the sample.

The detection zone of May is manually moveable (i.e. physically movable) in sequence from a first position in communication with the first flow path through switch 11 to a second position in communication with the second flow path through expansible switch (as recited in claims 77-78). Thus, when the detection zone is in its first position the sample receiving zone is spaced downstream from the detection zone along the first flow path and there is flow of the sample in the mobile phase from the sample receiving

zone to the detection zone, whereby the analyte is allowed to substantially bind with the immunoadsorbent.

Furthermore, when the detection zone of May is in its second position there is flow of the labeled immunoreactive material in the mobile phase to the detection zone without passing through the sample receiving zone, whereby the labeled immunoreactive material is allowed to substantially bind to the analyte, so as to provide an indication of the presence of the analyte in the sample.

With respect to the "Markush-type" claims 79-81, the first flow path includes a material selected from the group consisting of unlabeled immunoreactive material being upstream of the sample receiving zone (see col. 6, lines 55-62).

Regarding claims 82-85, 99-100, the first and second flow paths of May et al., potentiate flow towards the detection zone by capillary action (see col. 8, lines 2-4).

With respect to claims 86-89, written in a Markush format, May teaches a material absorbent to the mobile phase as disclosed beginning at col. 1, line 37.

Regarding claim 90, the apparatus of May includes a sink 9 for collection of fluid exiting the detection zone.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 92-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunce (US Patent No. 5,198,193) or May (US Patent No. 5,275,785) in view of Burd et al. (US Patent No. 5,939,331), hereinafter "Burd".

The teachings of Bunce and May have been summarized previously, *supra*.

Neither Bunce or May explicitly teach the analyte is allergen specific IgE (claim 92) or the removal of non-IgE components via a matrix or filter located between the sample inlet and the detection zone. However, the use of lateral flow assay for the IgE analyte in whole blood employing a filter is considered conventional in the art, see Burd.

Burd teaches a lateral flow device for detecting the presence of analytes (including IgE). The flow device includes a filter containing a matrix (i.e., red blood cell binding reagents) located at the sample receiving zone 23 between the sample introduction aperture 35 and the detection zone 29 (see col. 9, line 57- col. 10, line 14 and col. 7, lines 41-51). The filter is designed to remove the red blood cells since whole

blood sample may obscure the reading of the test results due to turbidity and color (col. 1, lines 19-20.)

Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the lateral flow device of Bunce, or May, the filter containing matrix of Burd, in order to remove the red blood cells since whole blood sample may obscure the reading of the test results due to turbidity and color (col. 1, lines 19-20.)

Response to Arguments

11. Applicant's arguments filed March 13, 2008 have been fully considered but they are not persuasive.

With respect to the previous rejection of claims 75, 77-90 and 99-102 under 35 U.S.C. 102(b) as being anticipated by Bunce (US Patent No. 5,198,193), Applicant points to the embodiment of Fig. 1 in Bunce as evidence that Bunce does not teach or suggest an apparatus configured to allow immunoreactive material to flow to a detection zone and bypass the sample receiving zone as required by claim 75.

The Examiner respectfully disagrees with Applicant's assertion. First, as pointed out in the previous Official action, dated November 13, 2007, the Examiner relies on the embodiments of Figs. 5 and 20 of Bunce for the teaching of an apparatus configured to allow immunoreactive material to flow to a detection zone and bypass the sample receiving zone, see above rejection.

Also with respect to the rejection claims 75, 77-90 and 99-102 under 35 U.S.C. 102(b) as being anticipated by Bunce and the rejection of claims 75, 77-90 and 99-102 under 35 U.S.C. 102(b) as being anticipated by May (US Patent No. 5,275,785), Applicant argues that the hydrated material is responsible for the movement between flow channels, rather than a “manual movement” as recited in amended claim 75. Applicant alleges that the devices of Bunce and May are intended to avoid the perceived difficulties associated with the use of devices involving "complex manual procedures". Thus, Applicant concludes that the use of hydratable expansible materials renders “manual movement” of portions of the device unnecessary.

The Examiner respectfully disagrees with all of Applicant’s arguments. First, it is noted that the features upon which applicant relies (i.e., an operator which manually switch between flow paths) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Second, the Examiner asserts that the stated purpose of the instant invention is to overcome the problems associated with non-sequential immunometric assays by providing a self diagnosis apparatus which can use a sequential immunoassay method, but which does not require sophisticated laboratory equipment or technical expertise, see page 4, lines 19-21 of specification as originally filed. This implies the operation of the instant inventive device by an operator is not required.

Lastly, claim 75, as currently amended, recites a detection zone including immunoadsorbent for binding the analyte when the analyte is present in the sample, the detection zone being manually moveable from a first position in communication with said first flow path to a second position in communication with said second flow path. The Examiner asserts the limitation being "manually moveable" does not necessarily mean "movement by an operator". The Examiner looks to the specification for what is meant by the phrase "manually movable". The only support for "manually movable" was found at page 13, lines 19-21, which states that after a specified period of time, typically ten minutes, and the second phase of reaction is initiated by the physical movement of the detection zone from the first flow path to the second flow path. This process may be carried out manually or by other means. That is, the phrase "manually movable" is not restricted to movement by an operator. The phrase "manually movable" has been interpreted as "physically movable" by the Examiner. Thus, the devices of Bunce and May, do teach a detection zone i.e., liquid-swellable material that is physically movable to make or break contact between two liquid-conductive zones.

Accordingly, for the reasons delineated above, the rejections of all pending claims is maintained.

Conclusion

12. No claim allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is 571-272-

2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

pkw

/Jill Warden/
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